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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,202	01/20/2006	Lasse Leino	OHMAN006	9235

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EXAMINER	
TEALE, MICHAEL J	
ART UNIT	**PAPER NUMBER**
4133	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,202	LEINO ET AL.	
	Examiner	Art Unit	
	Michael J. Teale	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejection - 35 USC § 112, First Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for preventing cancer, tumors or cellular proliferation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The burden of enabling the prevention of preventing cancer, tumors, or cellular proliferation would be much greater than that of enabling the treatment thereof. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing cancer, tumors, or cellular proliferation in general, or how a patient could be kept from ever being susceptible to these conditions. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing cancer, tumors, or cellular proliferation.

The term "prevention" or "preventing" may be reasonably interpreted as being synonymous with the term "curing" (see MPEP § 2111) and both circumscribe methods of treatment having absolute success. Since absolute success is not reasonably possible with most diseases/disorders, especially those having etiologies and pathophysiological manifestations as complex as cancer, the specification, which lacks a showing that cancer, tumors, or cellular

proliferation could actually be prevented, is viewed as lacking an adequate enabling disclosure of the same.

The present specification is evaluated by the Examiner as directed by the Court in *In re Marzocchi et al.* , 169 USPQ 367 (CCPA 1971):

"Specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that cancer, tumors, or cellular proliferation could be actually prevented is doubted because the term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success and because absolute success is not reasonably possible with most diseases/disorders.

One of ordinary skill in the art doubt that cancer, tumors, or cellular proliferation may be kept from ever occurring because these conditions are brought about by mutation, which cannot be prevented. Since the specification does not provide support or disclosure on how one of ordinary skill in the art would prevent mutations from occurring, it would be impossible for some of ordinary skill in the art to practice the invention.

Also, in claim 27 the claim language is confusing for several reasons: 1) is it the composition that is "able to acidify the cell cytoplasm" or is it "a pharmaceutically acceptable agent" that performs the function? Also the pharmaceutically acceptable carrier, (which is one of 4 components) "which carrier essentially prevents the enhancer from dissociating at extracellular ph values" does not clearly set out exactly what it is not dissociating from. In general the claim

is so unclear that it is impossible for the examiner to unravel the meaning of it and thus properly search it, correction is required. Furthermore, extracellular pH values may change significantly depending on where the cells are located.

Claims 26-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

These claims are drawn to a method of enhancing the effect of a therapeutically active agent. The specification does not contain a written description of the invention in that it does not disclose any method for **enhancing the effect of a therapeutically active agent**, and thus the applicant has failed to describe the invention in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

Claim Rejection - 35 USC § 112, Second Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17,18, 28, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.", (see MPEP § 2173).

The specification and claims disclose the use of any pharmaceutically acceptable acid with a "dissociation constant" range so broad it defies the idea of being called a constant. The only named compound (cis- or trans-urocanic acid) actually has two dissociation constants, and thus, it is not clear which proton applicant is claiming with a "dissociation constant".

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant claim 26, the term "said treatment" has no antecedent basis in the claim, correction is required.

Claim Rejection - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5494676 (Stab *et al.*) in view of US 6541509 (Horwitz *et al.*), and further in view of McDaid *et al.*

The claims of instant application are drawn to methods of preventing or halting cellular proliferation using urocanic acid (claims 16-25) and compositions containing cis- and/or trans urocanic acid (claims 27-33).

Stab teaches compositions of cis-urocanic and/or trans-urocanic acid and pharmaceutically acceptable salts thereof in treating human patients (Stab: claims 1-6 and col. 1, lines 57-67). Stab also teaches the treatment of dermatoses (abstract, col. 1, lines 11-21, and 49-56). In medicine, a dermatosis is a generic term for disease of the skin. The plural is dermatoses. Dermotoses covers all skin diseases including, skin cancer, eczema, psoriasis, acne, impetigo, scabies, sunburn, warts, fifth disease (also called erythema infectiosum or "slapped face disease"), tinea, herpes, ulcers, and pruritis. Halting cellular proliferation is certainingly one aspect of treating skin cancer (instant claim 16, 21, 22). The examiner notes here that dissociation constants are inherent properties of compound in general (claims 17-19, and 28-30). Due to the unclear nature of applicant's disclosure with respect to dissociation constants it is impossible to make any further claim analysis concerning applicants use of dissociation constants in the claims.

Stab does not explicitly teach the inherent anti-cancer properties of urocanic acid or its enhancer effects.

Horwitz and McDaid teach the anti-cancer effects of the urocnanic acid moiety (Horwitz: col. 10, lines 35-44) of a eleutherobin molecule (McDaid: abstract col. 2, p. 132 col. 1, p. 133

col. 2, p. 134 col. 2, and p. 135 col. 2) citing experimental results that attribute all the biological activity to the urocnanic acid moiety. Eleutherobin is a natural compound with the cancer treatment like properties of Taxol.

It is clear from the art that a person having ordinary skill in the art would be well aware of advances in their art as they occur and would readily combine information from various sources within their art. Since, at the time of instant application, it was very well known that cis- and trans-urocananic acid could be used in compositions and given to humans for treating dermatoses (a set of diseases that includes skin cancer), and that the urocanic acid structure was responsible for the anticancer-like properties, it would have been obvious to some one of ordinary skill in the art to combine the teachings of the above mentioned art to make obvious the instant claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Teale whose telephone number is (517)272-6897. The examiner can normally be reached on 9:00 am to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571)272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJT

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER